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INTRODUCTION

Walter Reed Army Medical Center and the VA Rehabilitation Research and Development Service

I. In the past 4 years, over 1870 active and non-active military amputees have accessed non-VA US Army Medical Facilities.

II. In fiscal year 2002 alone, the VA received over 10,000 visits related to lower-limb amputation and over 700 related to upper-limb amputation.

III. In Operation Iraqi Freedom and Enduring Freedom alone, over 82 servicemen have experienced major or multiple limb loss resulting in an influx of traumatic injury amputees to Walter Reed Army Medical Center.

IV. We must apply cutting-edge healthcare technology during the acute phase of amputee treatment and for the life of these servicemen and women.

V. Amputee healthcare, specifically prosthetic research and design, has not kept pace with that of other research disciplines leaving amputee healthcare professionals at a disadvantage when taking care of these men and women.

VI. Walter Reed Army Medical Center and the Veterans Administration Office of Research and Development are taking the lead to develop mechanisms that will lead prosthetic research and development.

Background

In the past four (4) years over 1870 active and non-active military amputees have accessed non-VA US Army Medical Facilities. In fiscal year 2002, the VA received over 10,000 visits related to lower-limb amputation and over 700 related to upper-limb amputation. In OIFEF alone, over 82 servicemen have lost limbs. Many of these amputees have lost 2 or more limbs. Walter Reed Army Medical Center (WRAMC) and VA Medical Centers are faced with the short and long-term care of these dedicated men and women. However, practitioners at Walter Reed Army Medical Center (WRAMC) and within the VHA are at a distinct disadvantage:

- Current technological advances are under-utilized. Amputee healthcare professionals have not taken advantage of available computer technologies, electronics or advances in robotic technology. There is clearly a disconnect between advances in platform technology and what we see in the clinic today. Successful methods developed in Europe have not been thoroughly tested here in the United States.
- Prosthetic practice is an empirical field. Prosthetists, physical therapists and others are untrained in and underexposed to research. As a result, research, development and implementation of evidence-based prostheses and amputee rehabilitation programs is slow. Long-term amputee healthcare is in need of a theoretical framework that uses evidence as the basis for clinical decision-making.
- Amputee healthcare for servicemen as they move from active duty to civilian status is not contiguous.

The Solution
Walter Reed Army Medical Center and the Department of Veterans Affairs are joining forces to perform joint research initiatives that will address the nation's growing need for innovative and functional prostheses and to perform prosthetics outcomes research that will ultimately drive healthcare administration.

- **Osseointegration: Exploration of near-clinical advances that will promote best care for the amputee.** In a continual effort to bring amputees best practices in healthcare, the VA is exploring osseointegration by leading the charge on its investigation and eventual implementation. VA Rehab R&D has put together a multidisciplinary group of VA investigators, surgeons, physical therapists, patients and osseointegration specialists to develop a plan of action and timeline for the careful investigation and possible implementation of osseointegration pilot studies in the VA. Together with WRAMC, the VA will maintain an accurate database of information allowing us to track amputees most appropriate for new interventions when those interventions are safe and available.

- **CAD/CAM: Maximization and efficient use of VA technologies in prosthetic design, manufacture and fitting**. Computer-aided design and manufacture via optical and topographic measurements of residual limbs and milling of positive casts is a breakthrough in prosthetic manufacture and fitting. Despite this, CAD/CAM technology has not been efficiently utilized at 36 VA CAD sites and 7 VA CAM facilities. CAD/CAM systems provide unparalleled advantages over traditional hand-made techniques, such as providing a better fit and being time and cost efficient. In an effort to efficiently utilize existing systems and to enrich present technology, VA REHAB R&D has put together a multi-disciplinary group of CAD/CAM users, former VA CAD/CAM trainers, present VA employees and representatives from Otto Bock Health Care to explore several avenues to improving the healthcare of amputees using CAD/CAM. In addition, VA Rehab R&D and Otto Bock Healthcare have initiated a dialogue to update the technology of appropriate CAD/CAM research sites within the VA.

- **Continuing education: Dedication to Amputee Healthcare Practitioners at WRAMC and in the VA.** VA Rehab R&D is taking the lead to develop VA-based professional research and development training that will stimulate new ideas for creating, fitting, and distributing prostheses and will create an atmosphere open to embracing and testing the impact of recent advances. VA RR&D has invited a group of individuals in faculty positions in academia, recent students, for-profit development and the VA Employee Education System together to discuss the creation of VA amputee healthcare/prosthetics training grants. The goal of this initiative is to foster the development of diverse and highly qualified individuals that can assume leadership roles in limb loss clinical research by incorporating areas such as materials science, CAD/CAM, robotics, myoelectrics and tissue engineering. These individuals will also discuss the formation of an amputee healthcare training center and design a Request for Proposals that pique the interest of investigators pursuing research in amputee healthcare interested in developing learning technologies and curricula specifically geared toward issues unique to amputee healthcare and prosthetics development. Once underway, faculty from WRAMC will participate on a continual basis as well as other faculty members from VAMCs.

- **Upper-limb prostheses: Research and development of better fitting, more functional upper-limb prostheses.** Many of the servicemen returning from Iraq are faced with the loss of one or both arms. This presents amputee healthcare and prosthetics professionals with the challenge of caring for this, previously, unique population. VA Rehab R&D has put together a group of leading upper limb prosthetics research and design experts to identify questions in upper limb prosthetic development that beg investigation, barriers to use and unique solutions.

- **Platform technology in prosthetics: Installation of broadly enabling technologies in the VA.** In August of 2003, the VA Office of Research and Development issued a Request for Proposals to install two (2) Rehabilitation Engineering Platform Technology Centers focused on amputee healthcare in the VA. The exciting challenge was to fund centers that developed technology that could provide veterans with solutions that restore function and promote a sense of being made whole. Multidisciplinary teams focused on the development of functional neural prostheses, efficient microprocessors or user-friendly myoelectric control systems would receive core funding in the amount of $850,000 per year for five (5) years in addition to investigator initiated monies from the VA, NIH, DOD and other agencies to develop and incorporate their findings into functional solutions for amputees. Both acute care research paradigms and long-term care studies would be done at WRAMC and in the VA. Unfortunately, only two(2) responses to this solicitation were received and only one of those proposed to develop technology that could be applied to amputee health. Therefore, questions posed to the Platform Technology discussion section will center around whether a Platform Technology Center of Excellence is needed, if so, which lines of research and development should be followed, what expertise is needed to launch these plans etc.

- **Lower-limb I/Rehab: Exploration of problems associated with lower-limb prostheses and barriers to use.**
  Pursuit of technologically advanced prostheses has led to lighter, more durable, better fitting and more functional lower-limb prostheses. In addition to better materials science, micro and computer technologies have led to the development of the highly successful C-Leg® microprocessor knee system. But quite frankly, it doesn't matter what materials, technology or advancements have been incorporated into a particular prostheses if amputees give up their prosthetic limbs in favor of wheelchair use or crutches. VA lower-limb prosthetic researchers, physical therapists from the VA, physical therapists from WRAMC, engineers and Director of the Mayo Clinic for Motion Analysis will discuss creative ways to study barriers to prosthetic use, ways in which physical therapists and others can promote ambulation and roles fellow lower-limb amputees play in promoting others to ambulate.

- **Lower-limb II: Introduction of current technological advances into amputee healthcare.** In conjunction with Otto Bock Healthcare, the short and long-term benefits of an active vacuum socket design, the Harmony VASS System will be tested at WRAMC and the VA. The Harmony VASS System "utilizes the normal step motion of the amputee to create an elevated vacuum pressure in specialized sockets, which acts to maintain limb volume by drawing blood and other fluids into the residual limb." Maintenance of blood flow, tissue oxygenation and maintenance of residual limb volume is critical for the prevention of secondary complications such as discomfort, ulcer formation and infection. These studies will be part of a collaborative effort between WRAMC and the VA, in which the continuum care of amputees ranging from acute at the WRAMC to long-term care at the VA will be assessed. A second study between WRAMC and the VA will examine the C-Leg® microprocessor-controlled knee-shin system in traumatic injury amputees from acute care into long-term use. Purportedly, the efficiency of the C-Leg's swing phase dynamics at varying speeds and on uneven terrain provides a more efficient secure gait than other systems. A third study using, again the Harmony VASS System, will be carried out as a multisite trial in the VA in veterans who have lost limbs due to diabetes or other circulatory problems. Specialists in lower limb prosthetics, gait analysis, faculty from WRAMC and the Director of the Cooperative Studies Program Coordinating Center in Perry Point will work together in their discussion group to design these studies.

- **Development of a WRAMC and VA amputee healthcare database.** This database put together by professionals from WRAMC, VA REHAB R&D and the Seattle Epidemiology Research Information Center will follow amputees as they move from active duty to civilian life promoting continuum of care through electronic record development and maintenance. This database will represent the first of its kind in optimum contiguous healthcare for the service-connected amputee. Discussion group members from the aforementioned groups as well as VA Centers of Excellence directors, the Director of Physical Medicine and Rehabilitation in the VA, personnel from the Department of Defense will work together in their group to develop a plan of action for efficient culling of necessary information and formation of a user friendly system.

Exploration of Near-Clinical Advances that will Promote Best Care for the Amputee

Osseointegration

I. Two key determinants of amputee success in adapting to a prosthetic system are comfort and psychological acceptance.
- **A.** Inconsistent fit from traditional cuff-like sockets often result in blisters, rashes, chafing and ulcers.
- **B.** Lack of psychological acceptance of the prosthetic limb results in a reluctant use, disuse and consequent decrease in ambulation.

II. Osseointegration, the direct attachment of titanium to bone of residual limbs allows for direct attachment of functional prostheses, bypassing the need for traditional cuff-like sockets. Osseointegration also promotes “osseoperception” or perceived sensation of the prosthesis.

III. Clinician researchers in Sweden and their amputee recipients report high levels of medical and personal success using osseointegration.

IV. Osseointegration is not FDA approved for use within the United States, preventing human subjects study.

V. The VA is interested in exploring the use of osseointegration as an alternative to current prosthetic management techniques.

Background

Osseointegration is a phenomenon discovered in the 1950s by Swedish bioengineer Per-Ingvar Brånemark, who discovered that titanium could integrate into bone without eliciting a rejection response and that the integrated titanium rod could be used to attach a functional prosthesis. Today, this technology has been capitalized upon in Europe and abroad. One Swedish amputee who has had bilateral osseointegrated titanium fixtures for 11 years reports no complications, as does an Italian policeman who lost both legs in a car bomb explosion. Both men lead active lives that include, hiking, biking, and rock climbing and report "osseoperception" or sensation of their prostheses.

Although European recipients report great success using this system, clinician scientists in the United States have expressed several concerns. For one, the long-term biomechanical feasibility of titanium has not been fully explored. Putting an extremely hard material, titanium, into a softer material, bone, creates stress mismatch, which could ultimately lead to loosening of the insert over time. Second, infection is a possibility. Maintenance of the fixtures requires that a patient keep clean the skin at the area of titanium bolt. Third, little is known about the effects of osseointegration in older patients with diabetes or vascular disease. Loosening, infection or dysvascularization could all lead to re-amputation or worse.

The Challenge

If osseointegration has the potential to be truly beneficial for the veteran amputee then how should the VA lead the charge on in its investigation and eventual implementation?

The Solution

The responsibility of the "Osseointegration" discussion group will be to develop a comprehensive 5 and 10 year plan of action and timeline for the careful investigation and possible implementation of osseointegration for veteran amputees. Areas of focus should include but not be limited to surgery, post-op care, short-term rehabilitation, long-term follow-up, secondary complications and accelerated studies to look at stress mismatch. Plans should include the best possible theoretical framework for such studies (series of pilots, consortium of researchers, multidisciplinary training grants etc), an outline for FDA approval, suggested academic partners, suggested industry experts etc. Presently, VA Rehab R&D supports "bottom-up" or investigator-initiated research projects in osseointegration and other subject areas. By designing plans "top-down" we can start with a vision that will take us to our goals faster, more efficiently and safer.

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1. Brånemark R, Brånemark P-I, Rydevik B, Myers RR. Review. Osseointegration in skeletal reconstruction and rehabilitation. J Rehabil Res Dev 2001;38:175-81.
2. Myers RR, Shubayev VI, Campana WM. Anatomy and pathology of the peripheral nervous system: Neuropathology of painful neuropathies. In: Sommer C, editor. Pain due to peripheral nerve diseases. Basel: Karger; 2001. p. 8-30.
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4. Myers RR. The role of cytokines in nerve injury and pain. In: E Williams, B Rydevik, R Johns, P-I Brånemark, editors. Osseoperception and musculo-skeletal function. Göteborg: Elixir Reklambyrå AB; 1999. p. 49-57.

Introduction, Maximization and Efficient Use Development of Current Technologies in Prosthetic Design, Manufacture, and Fitting

CAD/CAM in the VA

I. The potential utility and efficiency of Computer Aided Design and Computer Aided Manufacture (CAD/CAM) technologies were first demonstrated in 1983.
II. CAD/CAM technologies have been commercially available since 1994.
III. The VA placed CAD/CAM technology in 36 different VA sites in 1995.
IV. The VA has not efficiently incorporated CAD/CAM for clinical use.

Background
The idea of using computer-aided optical and topographic measurements of residual limbs to mass-produce prostheses was first introduced by James Foort in 1961. Since that time, there has been a burgeoning in technological advancements resulting in systems capable of rapid design and manufacture of prosthetics of equal or greater quality than those made using traditional hand-made techniques. Despite these advances, and its placement at 36 VA Medical Centers, CAD/CAM has not been is not widely or efficiently utilized in the VA Healthcare System.

The VA, as a large healthcare system, has not truly benefited from its initial investment in CAD/CAM technology completed in 1995. This is, in part, due to the lack of integration between these and other VAMCs, poor training of professionals, and the support of other less efficient, more expensive methods, employee turnover and the nature of prosthetics contract employment. Utilization of CAD/CAM technology will improve patient satisfaction. Formation of a collaborative network will result in quality control and continuum of care through electronic records. Educational investments will maximize existing technology resulting in efficient cost-effective use.

In September 2003, VA Rehab R&D and Otto Bock Healthcare initiated a dialogue to update the technology of appropriate CAD/CAM research sites within the VA and to develop a plan to create a consortium of the sites that would result in the aforementioned advantages. However, this is not enough. Upgrade of an underutilized system to an even better system will not necessarily result in its efficient use by VA contract and non-contract employees.

The Challenge
If the CAD/CAM technology already exists in the VHA then what how do we develop a research and implementation plan of action that will lead to its efficient use?

The Solution

The responsibility of the "CAD/CAM" discussion group will be to develop a comprehensive 1 and 3 year plan of action and timeline for the proof of principle and efficient incorporation CAD/CAM in the VA Healthcare System. Challenges include high employee turnover, poor training, contract employment of prosthetists uncomfortable with CAD/CAM and a lack of integration of the CAD/CAM systems in the VA. This plan of action should include but is not limited to upgrading of equipment by Otto Bock, training of contract and non-contract prosthetists, training of other non-contract full-time employees, implementation of apprentice-like programs to deal with employee turnover, incentives for contract prosthetists etc. Plans should include the best possible theoretical framework for such studies (ie formation of a functional network 1 VISN at a time etc), suggested academic or industry partners, plans for upgrading the system etc. The added challenge given to this group is to develop a TRANSLATIONAL RESEARCH plan of action that changes the "norm." in VA prosthetic healthcare.

References

1. CAD/CAM Systems in Pedorthics, Prosthetics & Orthotics, published by Verlag OrthopadieTechnik, Dortmund, Germany, 1998. (ISBN 3-931981-04-5).

FACILITY	*MC #*	*NAME*	*VISN*	*FACILITY ADDRESS*	*TELEPHONE*
Central Fabrication Sites					
Atlanta, GA	508	ALLEN, Gerald D	7	1670 Clairmont Road, Atlanta (Decatur), GA 30033	404-728-7626
Boston, MA	523	CHANDONNET, David J	1	150 South Huntington Avenue, Boston, MA 02130	617-232-9500x5825
Denver, CO	554	TREMAINE, Richard J	19	1055 Clermont Street, Denver, CO 80220-0166	303-393-4633
Dallas, TX	549	SCHWARTZ, Troy K	17	4500 South Lancaster Road, Dallas, TX 75216	214-857-0548
Houston, TX	580	BISHOP, Angela	16	2002 Holcombe Boulevard, Houston, TX 77030	713-794-7220
Manhattan , NY	630	LOOSEN, John M	3	423 East 23rd Street, New York, NY 10010	212-951-3245
Memphis, TN	614	GREENE-LOWRY, Dawn	9	1030 Jefferson Avenue, Memphis, TN 38104	901-577-7372
Miami, FL	546	FIELDS, Dwight	8	1201 Northwest 16th Street, Miami, FL 33125	305-324-3109
Richmond, VA	652	ECKARD, Ralph W	6	1201 Broad Rock Blvd., Richmond, VA 23249	804-675-5000 x3261
Brockton, MA	523A5	DESNOYERS, Edward	1	940 Belmont Street, Brockton, MA 02301	508-583-4500x1121
Satellite Sites					
Albuquerque, NM	501	GURULE, Felix S	18	1501 San Pedro, SE, Albuquerque, NM 87108	505-256-2756/2117
Bay Pines, FL	516	GARNER, Zellner	8	10000 Bay Pines Boulevard, Bay Pines, FL 33504	727-398-6661 x5545
Brooklyn, NY	527	VENDRELL, Maria	3	800 Poly Place, Brooklyn, NY 11209	718-630-3750
Bronx, NY	526	KLEIN, James	3	130 West Kingsbridge Road, Bronx, NY 10468	718-584-9000x5555
Buffalo, NY	528	CARUSO, John E	2	3495 Bailey Avenue, Buffalo, NY 14215	716-862-6357
East Orange, NJ	561	CLARK, Richard J	3	385 Tremont Avenue, East Orange, NJ 07018	973-395-7727
Hines, IL	578	HATTAWAY, Wanda D	12	Post Office Box 5000, Hines, IL 60141	708-202-8387 x21198
Indianapolis, IN	583	RILENGE, Michael W	11	1481 West 10th Street, Indianapolis, IN 46202	317-554-0605
Kansas City, MO	589	HINES, Betty M	15	4801 Linwood Boulevard, Kansas City, MO 64128	816-922-2628
Louisville, KY	603	SMITH, Gary L	9	800 Zorn Ave., Louisville, KY 40206	502-894-6182
Milwaukee, WI	695	BLUM, Karen M	12	5000 W. National Ave., Milwaukee, WI 53295	414-384-2000 x44124
Minneapolis, MN	618	HIIVALA, Charles	13	One Veterans Drive, Minneapolis, MN 55417	612-727-5632
Montgomery, AL	619	GERLACH, Roger D	7	215 Perry Hill Road, Montgomery, AL 36109-3798	334-260-4110 x4770
Nashville, TN	626	BROWN, ELAINE	9	1310 24th Avenue, South, Nashville, TN 37212-2637	615-327-5352
Oklahoma City, OK	635	BARLOW, Blake E	16	921 Northeast 13th Street, Oklahoma City, OK 73104	405-270-0501 x5612
Palo Alto, CA	640	CUMMINGS, R. Janelle	21	3801 Miranda Avenue, Palo Alto, CA 94304-1207	650-849-0353
Portland, OR	648	BUTTLES, Scott M	20	3710 S.W. US Veteran Hospital Rd, Portland, OR 97207	503-2203-438
San Antonio, TX	671	CORKWELL, Bradley D	17	7400 Merton Minter Blvd., San Antonio, TX 78284	210-617-5145
Seattle, WA	663	BAILEY, Ronald A	20	1660 South Columbian Way, Seattle, WA 98108-1597	206-762-1010 x63507
St. Louis, MO	657	THACKER, Patricia	15	#1 Jefferson Barracks Drive, St. Louis, MO 63125-4199	314-894-6645
Tampa, FL	673	FREYBERGER, Donald	8	13000 Bruce B. Downs Blvd., Tampa, FL 33612	813-978-5907
Temple, TX	674	VENEGONI, John	17	1901 South First Street, Temple, TX 76504	254-899-4005
Tucson, AZ		PHILLIPS, Clifford D	18	3601 South Sixth Avenue, Tucson, AZ 85723-0001	520-629-1828
West Los Angeles, CA	691	SAWYER, Steve	22	11301 Wilshire Boulevard, Los Angeles, CA 90073	310-268-4299
West Roxbury, MA	523A4	CHANDONNET, David J	1	1400 VFW Parkway, West Roxbury, MA 02132	617-323-7700 x6306
Wilkes Barre, PA	693	HANER, Eleanor S	4	1111 East End Boulevard, Wilkes Barre, PA 18711	717-821-7200

Dedication To Continuing Education of Amputee Healthcare Practitioners at WRAMC and the VA

I. Prosthetic practice is an empirical field. Clinicians are untrained in- and underexposed to research as well as underexposed to cutting edge technology commonly utilized in other fields.

II. The field of prosthetics is in need of a theoretical framework that uses evidence as the basis for clinical decision-making.

III. Prosthetists and other amputee healthcare professionals must incorporate novel methods and advancing technologies into their practice in order to provide best care for their patients.

IV. VA Rehab R&D is taking an active role in the development of professional education programs that provide research training necessary to develop evidence based practice guidelines and train practitioners to use the latest in technology developed in the United States and abroad.

Background

In order to continually provide veteran amputees with healthcare that addresses their unique acute care and long-term needs, amputee healthcare practitioners; specifically certified prosthetists, physical therapists and prosthetic researchers, must develop new skills. The field of prosthetics has languished behind that of other healthcare professions due to the lack of classical research training in their educational programs. As a result, prosthetics development is not driven by statistically significant outcomes research resulting in evidence-based practice. Add to that poor incorporation of platform technologies that promote functional use of upper limb prostheses and ambulatory lower-limb prostheses and we see that the state of the science is indeed poor.

The Challenge

If educational programs for prosthetists and other allied health professionals do not incorporate classical research training and continuing education classes do not expose these professionals to cutting edge technology what mechanisms do we develop that address these issues?

The Solution

VA Rehab R&D needs to take the lead by developing VA-based professional education training programs that expose amputee healthcare professionals at Walter Reed Army Medical Center and throughout VA Medical centers to classical research training techniques and innovative technologies. Creation of programs with these objectives in mind will create an atmosphere open to testing current practices, exploring the validity of anecdotal reports and to answering questions that beg investigation using creative methods and enabling technologies. The responsibility of the "Education" discussion group will be to determine:

1. the structure and steps necessary to create a multidisciplinary Amputee Healthcare Training Center. Plans should include but are not limited to best geographic location, format, necessary equipment, appropriate VA, academic and for-profit partners, foci, curricula, plans for continual improvement etc. The challenge will be to create a cost-effective ongoing format that supports the continual education of contract prosthetists, VA prosthetists and other allied healthcare workers associated with amputee healthcare. Educational technology, methodology, and theory will be the vehicle for research method and technology education in prosthetics.

2. the necessity and/or best components for a VA training grant in prosthetics. The challenge will be to outline the educational structure, academic atmosphere, facilities, and strategic learning plans necessary for the successful research and development mentorship of young amputee healthcare professionals.

The goal of these training programs will be to foster the development of diverse and highly qualified individuals that can assume leadership roles in limb loss clinical research by incorporating areas such as materials science, microprocessor technology, CAD/CAM, robotics and tissue engineering.

Research and development of better fitting, more functional upper-limb prostheses

I. Many of the servicemen returning from Iraq are faced with the loss of one or both arms.
II. This presents amputee healthcare and prosthetics professionals with the challenge of caring for this, previously, unique population.
III. VA Rehab R&D must develop plans for addressing the short and long-term healthcare needs of uni-and bilateral upper-limb amputees.

Background
In order to continually provide veteran amputees with healthcare that addresses their unique acute care and long-term needs, amputee healthcare practitioners and upper-limb prosthetic design researchers must explore creative solutions and incorporate enabling technologies to the development and fitting of upper limb prostheses. In some ways, research and development of upper-limb prosthetics has fallen behind research and development of lower-limb prosthetics. This is, in part, thankfully due to a decreased number of upper-limb amputees in recent years. Unfortunately, this is also due to barriers-to-use such as difficult bulky harness systems and therefore a lack of impetus for incorporating new technologies into the design of upper-limb prostheses not widely sold.

The Challenge
If technologies exist that can promote both the development and use of upper-limb prosthetic mechanisms and we are presented with the need for sophisticated user-friendly upper-limb prosthetic systems, especially for bilateral amputees, what do we do to promote the incorporation and development of these technologies into user-friendly systems?

The Solution
The responsibility of the “Upper-Limb” discussion group will be to determine which avenues need to be aggressively pursued in order to provide uni- and bilateral upper limb amputees with best care. Plans should include the best possible theoretical framework for such studies (series of pilots, Center of Excellence, multidisciplinary training grants etc), suggested academic partners, suggested industry experts etc. By creating a comprehensive shopping list of needs and necessary expertise, methods, materials and plans to address those needs we will overcome barriers to use and create better, more functional upper-limb prostheses. This group is encouraged to employ creative measures such as ethnographic studies to determine the needs of upper-limb amputees.

Installation of Platform Technologies at WRAMC and the VA

In August of 2003, the VA Office of Research and Development issued a Request for Proposals to install two (2) Rehabilitation Engineering Platform Technology Centers focused on amputee healthcare in the VA (see below). The exciting challenge was to fund centers that developed technology that could provide veterans with solutions that restore function and promote a sense of being made whole. Multidisciplinary teams focused on the development of functional neural prostheses, efficient microprocessors or user-friendly myoelectric control systems would receive core funding in the amount of $850,000 per year for five (5) years in addition to investigator initiated monies from the VA, NIH, DOD and other agencies to develop and incorporate their findings into functional solutions for amputees.

The Solution

The responsibility of the "Platform Technology" discussion group will be to brainstorm ways in which enabling technologies can be incorporated into the development of prostheses. Previous discussions with prosthetic research and development experts suggest this should be done via formation of a Platform Technology Center. However, response to the solicitation below was poor. Plans developed by this discussion group should include the best possible theoretical framework for incorporation of technology, (Platform Technology Center, multidisciplinary training grants etc), what technologies need to be pursued (myoelectric controls, microprocessor technology, combination of both), plans for how these technologies should be explored, suggested academic partners, suggested industry experts etc. The challenge will be to outline a plan of action that will result in continual incorporation of cutting-edge technology in prosthetics.

Solicitation Of Application For
Rehabilitation Engineering and Platform Technology Center

1. This Information Letter announces the opportunity for Department of Veterans Affairs (VA) medical facilities to submit proposals for establishing Rehabilitation Research and Development (RR&D) Centers that focus on engineering technologies to address sensory deficits, motor impairment or **limb loss**. These represent high priority areas relevant to the rehabilitation needs of veterans. ***NOTE:*** *Required format and instructions for submitting applications are provided on our website at www.vard.org.*

2. VA RR&D Centers are a resource for the rehabilitation research community, their host VAMCs and ultimately, the veterans. The proposed RR&D Centers are expected to provide cutting-edge translatable solutions to issues of sensory deficit, motor impairment or **limb loss**. Additionally, all centers must focus on health preservation. This is accomplished by cultivating a productive interactive community of VA clinician scientists and scholars to build human capacity, train personnel to practice in a multidisciplinary environment, share their intellectual and physical resources, incorporate best methods and take a proactive comprehensive approach to rehabilitation of the veteran.

3. Biomedical and rehabilitation engineering technologies are rapidly growing. Centers must embrace, incorporate and advance technology. VA researchers, staff physicians, manufacturers and VAMC administrators must work side-by-side to through all phases of development, testing, manufacture and implementation to ensure that creative approaches are used and best practices and incorporated. **The exciting challenge is to provide veterans solutions that restore function and promote a sense of being made whole.**

4. Proposals that incorporate materials science, CAD/CAM, microtechnology, neural prostheses, robotics, tissue engineering, molecular biology and other emerging biomedical engineering applications are expected and encouraged.

5. **Proposals that incorporate therapies and technologies to promote amputee healthcare or are used in the development, fit and maintenance of prostheses are greatly encouraged.**

6. Centers are to develop an integrated thematic research core as a unifying focus of research activities with a well-reasoned 5-year plan. Centers will use program funding (822). The applicant will be solely responsible for planning, directing, and executing the proposed project. The applicant may request up to $750, 000 direct costs per year. This Solicitation is in accordance with 38 U.S.C $7303.

7. This solicitation will not support Centers based predominantly at non-VA sites.

8. VA RR&D Centers are expected to:

    a. Become nationally recognized "Centers of Excellence" in a selected area of research relevant to veterans with disabilities.

    b. Successfully leverage core support funding through nationally competed and scientifically reviewed funding vehicles: VA investigator-initiated programs, Federal granting agency programs, private foundation awards, and collaborations with commercial partners.

    c. Mentor and support young investigators, both clinician and non-clinician scientists, through pre- and post-doctoral programs and recruit them into VA.

    d. Nurture strong interactive relationships with the appropriate VA medical facility clinical service providers engaged in rehabilitation, long-term management of impairment and quality of life issues.

    e. Maintain collaborative partnerships of mutual benefit to the VA, the VA medical facility, and the supporting community institutions (e.g. schools of medicine, allied health sciences, manufacturers, and non-profit patient support systems).

    f. Facilitate effective information dissemination for a broad spectrum of audiences.

    g. Foster integration of research findings into clinical practice throughout the healthcare delivery system.

    h. Actively participate in the national consortium of VA RR&D Centers to strengthen natural collaborative bonds and to advance RR&D in the scientific community and national consciousness.

9. Current foci of RR&D Centers are Visual Impairment and Aging (*Atlanta*); Innovative Visual Rehabilitation (*Boston*); Rehabilitation Outcomes –Stroke (*Gainesville*); Bone & Joint (*Palo Alto*); Amputation, Prosthetics and Limb Loss Prevention (*Seattle*); Rehabilitative Auditory Research (*Portland*); Functional Electrical Stimulation (*Cleveland*); Medical Complications of SCI (*Bronx*); and Functional Recovery in SCI (*Miami*).

10. In addition, VA RR&D funds three Research Enhancement Award Programs (REAPs) in Audiology (*Mountain Home*); Tissue Engineering (*Boston*); and Technology for "At-Risk" Patients (*Tampa*).

11. Any VA medical facility (or consortium of VA medical facilities) with significant rehabilitation research capacity and with well-established academic partnerships is encouraged to apply. Maximum VA RR&D awards of core funding will be up to $850,000 annually, with required competitive renewal on a 5-year cycle. Up to $7,000 per year of the award can be requested for travel to professional meetings.

12. Each center will have a Director and an Associate Director for Research with doctoral degrees and at least a 5/8ths VA appointment. Either the Director or Associate Director must be a clinician with medical care funds committed by the host VA medical center in support of clinician salary. The medical and scientific leadership are expected to:

    a. Identify research goals and objectives within a given focus are and direct research plans towards achievement of specified goals and objectives. Research plans need to include collaborative activities.

    b. Develop a five-year research program with specific aims directed toward new discoveries that have the potential to impact clinical practice.

    c. Achieve maximal administrative efficiencies, control and reporting capabilities, project monitoring, and leveraging of limited core support funds at local and national levels

    d. Support the growth and enhancement of vigorous and creative "learning environment." Maintain information dissemination activities that promote findings from RR&D Centers.

13. VA RR&D Center proposals will be scientifically reviewed for merit to objectively determine relevance of the proposed research to the veteran population, capability of the applicant to meet the intended outcome of proposed research program, and potential contribution of proposed research to the field of rehabilitation, long-term management of impairment, and overall quality of life issues for veterans with disabilities. Criteria for review and evaluation are:

    a. **Strength of Proposed Research Focus**. Includes the:
       (1) Relevance to veteran population,
       (2) Relationship of proposed research activities to announced research focus,
       (3) Potential of proposed research to produce new and useful information,
       (4) Clarity and ability to execute the research plan, and
       (5) Contribution to overall VA RR&D portfolio.

    b. **Effectiveness of Operating Plan**. Includes the:
       (1) Ability to achieve intended research outcomes,
       (2) Ability to coordinate the proposed collaborations and evidence of their benefit to VA and veteran healthcare,
       (3) Feasibility of evaluation and quality assurance methods,
       (4) Sufficient coverage of all required disciplines,
       (5) Ability to build research capacity within VA, and
       (6) Effectiveness of plan to disseminate research findings.

c. **Adequacy of Resources**. Includes the:
   (1) Scientific strength of current VA Research and Development (R&D) Program, especially in rehabilitation research,
   (2) Vitality of rehabilitation clinical base within VA medical facility,
   (3) Support and demonstrated commitment of VA medical facility(s) and cited affiliations,
   (4) Demonstrated scientific/engineering/medical leadership of key personnel at VA,
   (5) Evidence of VA-based core of investigators, and
   (6) Adequacy of VA facilities and equipment.

d. **Budget and Cost Effectiveness**. Include the:
   (1) Ability to support program activities,
   (2) Reasonable costs, and
   (3) Appropriateness and detail of subcontract budget (if required).

14. General guidelines for applicants are:

a. All Center funding awards are contingent on availability of funds.

b. All applicants must submit a **Letter of Intent to apply by October 1, 2003**. LOIs must be directed through the ACOS/Research and include names of key investigators, certification from the facility that the principal investigators have at least 5/8th VA appointments, certification that space will be provided at the VA facility to support the proposed center.

c. The R&D Committee before submission must review all applications. If a Center is awarded, appropriate response from Human Subject, Animal Safety and BioSafety Subcommittee reviews and approval will be required before funding.

d. Applicant sites may be a single VA medical facility or a consortium of collaborating VA medical facilities. Consortium applicants must identify a lead site with a well-established academic partnership. Organizational relationships and responsibilities of consortia are to be clearly delineated.

e. Scientifically approved proposals will require administrative site visits in advance of making definitive funding determinations.

f. The Director and Associate Director must be eligible to receive VA research support (eligibility must be established prior to submission of the proposal).

g. Annual (non-competing) progress reports for the Center will be reviewed administratively by RR&D Service to monitor performance against stated program plans. ***NOTE:*** *Unsatisfactory performance will result in probationary status or termination of funding*.

15. All funding is dependent upon the availability of funds.

16. The timeline for proposal submission, review and award is:

a.	**Letters of Intent:**	**October 1, 2003**
b.	**Proposals due in VHA Headquarters:**	**January 15, 2004**
c.	**Review:**	**April 2004**
d.	**Administrative site visits:**	**June 2004**
e.	**Final Notification of Awards:**	**June 30, 2004**
f.	**Projected Funding (for new Centers):**	**July 1, 2004**

17. Questions concerning this solicitation for proposals may be directed to: Danielle M. Kerkovich, Ph.D., Acting Assistant Director for RR&D.

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Exploration of problems associated with lower-limb prostheses and barriers to use
Lower Limb I/Rehab

I. Pursuit of technologically advanced prostheses has led to lighter, more durable, better fitting and more functional lower-limb prostheses.
II. In addition to better materials science, micro and computer technologies have led to the development of the highly successful C-Leg® microprocessor knee system.
III. But quite frankly, it doesn't matter what materials, technology or advancements have been incorporated into a particular prostheses if amputees give up their prosthetic limbs in favor of wheelchair use or crutches.
IV. Barriers to use such as inconsistent fit, lack of psychological acceptance and poor use need and can be overcome with proper training of amputees and healthcare professionals.

Background
In order to promote effective use of lower-limb prostheses and ambulation the VA must take the lead on identifying the barriers-to-use are and in turn, formulate creative feasible solutions that stand up to the rigors of scientific investigation, can be easily incorporated into the rehabilitation plans of the amputee and are cost-effective.

The Challenge
If technologies exist that can promote both the development and use of lower-limb prostheses why do so many amputees give up their prostheses in favor or wheelchair use or crutches?

The Solution
The responsibility of the "Lower-LimbI/Rehab " discussion group will be to identify the barriers-to-use of current prostheses and to develop research proposals that address those barriers in creative, healthcare setting and amputee user-friendly ways. For example, it is clear that amputees require training to efficiently use their prostheses. However, many receive little physical therapy by individuals who are poorly prepared to deal with their issues. Anecdotal evidence from amputee running clinics suggests that amputees can use their limbs inefficiently for many years but bad habits can be broken and may best be broken when amputees learn from one another. Testing of amputee to amputee walking clinics could represent a creative cost-effective way of providing rehabilitation. Plans should include the best possible theoretical framework for such studies (clinics, series of pilots etc), suggested academic partners, suggested industry experts, suggested healthcare provider specialties etc. By creating a comprehensive shopping list of why amputees fail to ambulate effectively and creative plans to address those issues that utilize all available expertise, we will overcome barriers to use. This group is encouraged to employ all aspects of short and long-term rehabilitation.

Introduction of Current Technological Advances Into Amputee HealthCare

Better Lower-Limb Prostheses in the VA
Lower Limb II

I. One key determinant of amputee success or failure to adapting to a prosthetic system is the socket, the interface between residual limb and prosthetic limb.

II. A socket must provide stability, facilitate ambulation and most importantly, fit well and be comfortable. If a socket is not comfortable, does not promote the health of the individual and results in tissue breakdown, the componentry to which it is connected is useless.

III. Although research has progressed in the fields of biomechanics and materials science resulting in new-age nanofabrication techniques and myoelectric limbs, socket design remains a challenge. This is especially true for special populations with poor circulation such as poorly vascularized veterans.

Background

Lower-limb amputees experience a myriad of problems on a daily basis, not the least of which is the very common and painful problem of tissue breakdown associated with traditional cuff-like prosthetic design. Oftentimes, these problems are further compounded by normal volume fluctuations in the residual limb resulting in chronic problems with blisters, chafing, rashes and even ulcers. For many amputees mobility is limited to only a few steps at a time before pain becomes unbearable, and between 25 and 35 percent of them give in to the chronic pain and give up ambulation.

For amputees suffering from diabetes or cardiovascular disease, which are the leading causes of lower limb amputation in the VA, tissue breakdown can lead to more serious medical complications. Veterans with diabetes-induced peripheral neuropathy cannot easily detect skin breakdown, leading to infections and possible reamputation.

The Challenge

To provide veterans with lower-limb loss, a well-fitting prosthesis that helps control volume fluctuation in the residual limb, reduces forces to the residual limb, and helps reduce moisture build-up and ensuing skin deterioration.

The Solution

I. In October 2003, VA Rehab R&D and Otto Bock Healthcare initiated a dialogue to test the short and long-term benefits of an active vacuum socket design, the Harmony VASS System. This system by Otto Bock utilizes the normal step motion of the amputee to create vacuum pressure within the socket. Purportedly, this pressure then maintains limb volume by drawing blood and other fluids into the residual limb.

A. Clinician scientists at VA Medical Centers and Walter Reed Medical Center staff will undertake a joint multi-site project examining the overall health benefits of using the Harmony VASS System in lower limb amputees returning from Iraq. Analyzing blood flow, tissue oxygenation, and maintenance of residual limb volume during acute and post-acute care stages will answer important questions regarding the efficacy of this system and need for new developments.

B. Due to the proposed perfusion/reperfusion benefits of the Harmony VASS System, this system will also be studied for use with vascular compromised veterans. In contrast to the VA REHAB R&D/Walter Reed pilot project, this study will be a long-term multi-site

analysis. VA diabetic and cardiovascular populations, hopefully, will benefit the most from long-term use of this system.

The Challenge of the Lower Limb II discussion group will be to design these studies along with studies that examine the use of the C-Leg® in traumatic injury amputees from the acute care stage at WRAMC into the VA.